

REMARKS/ARGUMENTS

Claims 1-30 and 32-55 are pending in the instant application. Of these, claims 2, 25, 29 and 54 are examined and claims 1, 3-24, 26-28, 30, 32-53 and 55 are deemed withdrawn from consideration.

Claims 2 and 27 are currently amended. No new matter has been added.

The Examiner has argued that claim 27 (and by implication claim 55) should be deemed withdrawn based on Applicants' previous election of cyclosporin as the active ingredient. In response, Applicants have amended claim 27 herein to avoid this alleged inconsistency.

With regard to the Examiner's withdrawal of claim 53, and allegation that "in electing a specific composition (filed 7/30/01) Applicants provided no indication that there might be a gelatin capsule present" (Office Action at page 2), Applicants respectfully submit that claim 53 is actually a recitation of claim 31 which was included among the claims of Group II per the Restriction Requirement of June 28, 2001, and Group II was subsequently elected by Applicants for prosecution on the merits in the instant application. Furthermore, Applicants respectfully submit that Applicants were only required to elect one of Groups I-IV for prosecution on the merits, and a *species* for prosecution. There was no requirement that Applicants elect a "specific composition" as alleged. Applicants therefore respectfully submit that claim 53, directed to the formulation of claim 2 contained in gelatin capsule, should be included among the claims for examination.

REJECTION UNDER 35 U.S.C. § 112:

Claims 2, 25, 29 and 54 are currently rejected under 35 U.S.C. §112, first paragraph, in view of Applicants' previous amendment to claim 2 to recite that R' is an acyl group.

In order to further prosecution, Applicants have amended claim 2 herein to restore the term *alkyl*, thus obviating this rejection.

REJECTION UNDER 35 U.S.C. § 103:

Claims 2, 25, 29 and 54 are rejected under 35 U.S.C. § 103 as being unpatentable over *Stuchlik*, WO 98/10747 (hereinafter "*Stuchlik*").

The Examiner alleges that *Stuchlik* discloses, on page 4, compositions comprising cyclosporine and polyglycerol esters. Applicants have previously argued that *Stuchlik* does not teach use of a mixture of two polyglyceryl esters, one having an HLB value not greater than 9 and the other having an HLB value not less than 10. Specifically, *Stuchlik* does not disclose use of a polyglyceryl-3 ester of oleic acid having an HLB value of not greater than 9.

The Examiner alleges that such a composition is taught in *Stuchlik* at Example V on page 18, specifically, a composition having polyglycerol-10-monooleate as a polyglycerol ester with an HLB value at least 10 and polyglycerol-3-monooleate as a polyglycerol oleate ester having an HLB value less than 9.

*Stuchlik* may disclose compositions comprising cyclosporine and polyglycerol esters, however, the teachings of the cited reference are insufficient to render the claimed formulations obvious. Specifically, Applicants submit that Example V discloses a composition containing, among other things, "decaglyceryl monolaurate" and "diglyceryl monooleate". Diglyceryl monooleate, however, is polyglyceryl-2 oleate, not polyglycerol-3-monooleate; it is not a polyglyceryl-3 ester of oleic acid. (See, Exhibit 1). Rather, polyglyceryl-3 monooleate is "triglycerol monooleate." (See, Exhibit 2).

Applicants respectfully submit that the Examiner has previously conceded that *Stuchlik* does not disclose the specific ratio of components taught in the instant invention. (Office Action dated July 9, 2008 at page 3). Applicants have

previously asserted, and reiterate hereinabove, that *Stuchlik* does not even describe the exact components disclosed in the instant invention. As all the claimed elements are not disclosed in *Stuchlik*, a *prima facie* case of obviousness has not been established. Thus, Applicants respectfully request reconsideration and withdrawal of all outstanding claim rejections under 35 U.S.C. §103.

As it is believed that all of the rejections set forth in the Office Action have been fully met, favorable reconsideration and allowance are earnestly solicited. If, however, for any reason the Examiner does not believe that such action can be taken at this time, it is respectfully requested that he telephone Applicants' attorney at (908) 654-5000 in order to overcome any additional objections which he might have.

A petition for a one-month extension of time is submitted with this amendment. If there are any additional charges in connection with this requested amendment, the Examiner is authorized to charge Deposit Account No. 12-1095 therefor.

Dated: July 30, 2009

Respectfully submitted,

By *Diane P. Tso*  
Diane P. Tso

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## DIGLYCERYL MONOOLEATE

### PRODUCT IDENTIFICATION

CAS NO. 49553-76-6  
 EINECS NO. 256-367-4  
 FORMULA  $C_{24}H_{46}O_6$   
 MOL WT. 430.62

H.S. CODE

TOXICITY

SYNONYMS

Polyglyceryl-2 oleate;

Diglycerol monooleate; 9-Octadecenoic acid, monoester with oxybis(propanediol); Oleic acid, monoester with oxybis(propanediol); 9-Octadecenoic acid, ester with 1,2,3-propanetriol (1:2); (3-(3,3-dihydroxypropoxy)-1-hydroxypropyl) (2)-octadec-9-enoate;

DERIVATION

CLASSIFICATION

PHYSICAL AND CHEMICAL PROPERTIES

PHYSICAL STATE yellowish wax

MELTING POINT

BOILING POINT

SPECIFIC GRAVITY

SOLUBILITY IN WATER

pH

VAPOR DENSITY

REFRACTIVE INDEX

INFLAMMATORY RATINGS

AUTOIGNITION

FLASH POINT

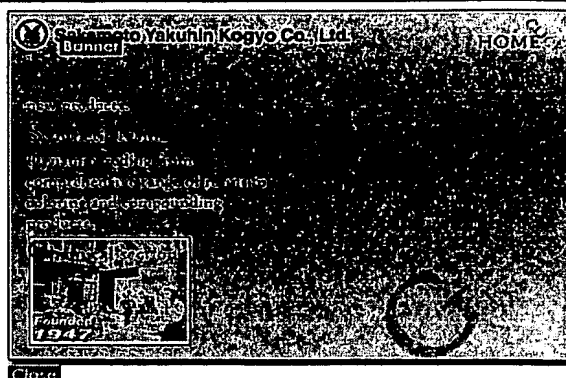
STABILITY Stable under normal conditions.

### GENERAL DESCRIPTION & APPLICATIONS

An emulsion is a mixture of two repel substances (water and oil). It induces a dispersion of undissolved material throughout a liquid. The dispersed phase is dispersed in the other continuous phase. Emulsions are unstable and thus tend to revert to the stable state of oil separated from water spontaneously. Physical energy such as shaking, stirring, homogenizers, or spray processes is needed to keep an emulsion. Surfactants increase the kinetic stability of emulsions and make the emulsion does not change significantly for long term. An emulsifier is a type of surfactant used to keep emulsion stable and well dispersed. Emulsifiers typically have a hydrophobic head and a hydrophilic tail in one molecule. The emulsifiers will surround on hydrophobic molecule and hydrophilic tail form a protective layer so that the oil molecules cannot "clump" together. This action helps keeps phase well dispersed. Some of the most important emulsifiers include salts or esters of higher fatty acids, fatty alcohols, esters of monoglycerides, gelatin, lecithins, polysaccharides and casein.

Glycerides (also known as acylglycerols) are esterified to glycerol with fatty acids. Glycerol having three hydroxyl functional groups is esterified with one, two or three fatty acids to form monoglycerides, diglycerides and triglycerides respectively. A monoglyceride is a compound consisting of one fatty acid chains covalently bonded to a glycerol molecule through ester linkage. Diglyceride and triglyceride consists of two and three fatty acid chains respectively. Examples of triglyceride include triacetin, trimyristin, and triolein. Monoglyceride usually occurs as an intermediate in triglyceride metabolism by means of a release of a fatty acid from lipase. The commercial source may be either animal or vegetable fats, and synthetically produced as well. Mono- and diglycerides are common food additives used as an emulsifier or stabilizer to blend together certain ingredients of oil-hating and water-hating, which would not otherwise blend well.

Emulsifier	CAS RN.
Cholesterol	57-88-5
Metalkonium chloride	100-95-8
Dinitrosopentamethylenetetramine	101-25-7
Laurosept	104-73-4
N,N-Dimethyl-1-dodecanamine	112-18-5
Dodecylamine	124-22-1
Triethanolamine lauryl sulfate	139-96-8
Oleyl alcohol	143-28-2
Sodium Lauryl Sulfate	151-21-3
Dodecyl sulfate	151-41-7
Laurylbetain	683-10-3
Hexadecylbetaine	693-33-4
Sodium stearate	822-16-2
Sodium tetradecyl sulfate	1191-50-0
Propylene glycol monostearate	1323-39-3
Sorbitan monooleate	1338-43-8
Sorbitan monostearate	1338-41-6
Sorbitan monolaurate	1338-39-2
Dodecylsulfonic acid	1510-16-3
Dodecyltrimethylamine oxide	1643-20-5
Dihexadecyldimethylammonium	1812-53-9
Pentaethylene glycol monododecyl ether	3055-95-6
Hexaoxyethylene dodecyl ether	3055-96-7
Tergitol 7	3282-85-7
Hexadecyl phosphate	3539-43-3
N-Lauroyl-N-methyltaurine	3737-57-3
Dodeconium	3818-69-7



n-Decyl phosphoric acid	3921-30-0
2-O-Rhamnopyranosyl-rhamnopyranosyl-3-hydroxydecanoyl-3-hydroxydecanoate	4348-76-9
Distearoyl phosphatidylglycerol	4537-78-4
N-(2-Hydroxy-3-[(2-methyl-1-oxoallyl)oxy]propyl)-N-phenylglycine	4896-81-5
Cetyl sulfonic acid	6140-88-1
Dadacil	6843-97-6
Tetradecyltrimethylphosphonium	7368-64-1
Oxychlorosene	8031-14-9
Polyethylene glycol 2000 sorbitan lanolate	8036-77-9
Gelatin	9000-70-8
Octoxynol 9	9002-93-1
Polyacrylic acid	9003-01-4
Povidone	9003-39-8
Pegoterate	9003-68-3
Poloxalene	9003-11-6
Carboxymethylcellulose Sodium	9004-32-4
Caloreen	9004-53-9
Hydroxypropyl cellulose	9004-64-2
Polyoxyl 8 stearate	9004-99-3
Hydroxyethyl cellulose	9004-62-0
Polyethylene glycol (14) cetyl ether	9004-95-9
Methylcellulose [USAN:INN:JAN]	9004-67-5
Polyoxyethylene monolaurate	9004-81-3
Polyethylene glycol myristate	9004-89-1
Hydroxypropyl methylcellulose	9004-65-3
Sodium Alginate	9005-38-3
Octadecyl polyoxyethylene ether	9005-00-9
Alginic acid	9005-32-7
Polyoxyethylene-glycerin monostearate	9011-21-6
polyethylene glycol alkylphenyl ether	9041-29-6
Docusate hydrogen	10041-19-7
Tetradecyltrimethylammonium	10182-92-0
Dodecyltrimethylammonium	10182-91-9
Ethylene Oxide/Propylene Oxide Block Copolymer	11111-34-5
30-Oxyethylated 1-octyl phenol formaldehyde tetramer	12584-89-3
Texapon	12656-15-4
Creolin	12751-04-1
N-Octanoylglucosylamine	13287-92-8
Dimethyldioctadecylammonium	14357-21-2
N-Myristyl-beta-aminopropionate	14960-08-8
Stearamidoethyl diethylamine	16889-14-8
Laxagetten 4,4'-diacetoxydiphenylpyridylethane	18869-73-3
Ethonium	21954-74-5
Polyamithine	25104-12-5
Tyloxapol	25301-02-4
Polyoxyethylene nonylphenyl ether	26027-38-3
Dodecyl polyoxyethylene sulfuric acid	26183-44-8
Sorbitan monopalmitate	26266-57-9
Sorbitan trioleate	26266-58-0
Prepodyne	26617-87-8
Phosphated nonylphenoethoxylate	26912-46-9
Dodecylbenzenesulfonic acid	27176-87-0
Monolaurin	27215-38-9
Polyoxyethylene-24-cholesteryl ether	27321-96-6
Mixidine	27737-38-8
1-Undecylpyridinium	29633-39-4
Sodium sulfuricinate	29704-46-9
Glycerol monostearate	31566-31-1
Cetyl alcohol	36653-82-4
Rhamnopyranosyl-3-hydroxydecanoyl-3-hydroxydecanoate	37134-61-5
Sorbitan sesquileate	37318-79-9
p-Menthanylphenyl polyoxyethylene ether	38193-77-0
Ethoxylated dioctylphenol	39278-93-8
Sulfopone	39341-49-6
N(alpha)-Lauroylarginine ethyl ester	48076-74-0
Laurylsarcosyltaurine	50613-54-2
Macrocydon	51273-01-9
N-(1-Methyldodecyl)-N,N,N-trimethylammonium	52234-85-2
Polyoxyethylene isostearyl ethers	52292-17-8
[Carboxymethyl]dodecyltrimethylammonium chloride	55142-08-0
Ammonium phosphatides	55965-13-4
Polyoxyethylene-glycerin-monooleate	57107-97-8
N-Stearoyltyrosine	57993-25-6
N,N-Dimethyl-1-methyldodecylamine oxide	60729-78-4
Polyoxyethylene castor oil	61791-12-6
Neonol	63035-21-2
Isopropyl lanolin	63393-93-1
Benzyl alkyl(C10-18) dimethyl, ammonium chlorides	64365-16-8
Potassium nonan-5-sulfate	66091-08-5

4-(1'-Heptylnonyl)benzenesulfonate	67267-95-2
Pareths	68131-39-5
Ditallow dimethylammonium	68783-78-8
(N-Dodecyl-N,N-dimethylammonio)undecanoic acid	73025-13-5
O,O'-Didodecyl-N-(4-(2-trimethylammonioethoxy)benzoyl)-glutamate	79508-19-3
Delmapinol	79874-76-3
Octyl maltopyranoside	82494-08-4
1-Deoxy-(N-methyloctanamido)-D-glucitol	85316-98-9
6-[4-Vinylbenzyl-n-propyl]amino-1,3,5-triazine-2,4-dithiol	88373-30-2
Perfluoro-C4-8-alkylsulfonic acid amine salt	101027-19-4
Poloxamer	106392-12-5
Poloxamer	106392-12-5
1,1,1,2,2,3,3,4,4,5,5,6,6,7,7,8,8-Heptadecafluoro-9-octadecene	113999-61-4
6-O-(N-Heptylcarbonyl)methylglucoside	115457-83-5
1-Deoxy-(N-methylundecanamido)-D-glucitol	119772-49-5
Glydip	122276-84-0
Imidastat O	126836-12-2
N-Laurylbiotinamide	128631-44-7
Desintegrin O	138673-63-9
Desintegrin B	138673-85-5
Helical erythrocyte lysing peptide	143780-69-2
Titernax	145380-33-2
1,1,1,2,2,3,3,4,4,5,5,6,6-Tridecafluorohexadecane	147492-59-9
Arthrofactin	152406-36-5
N-Dodecoxycarbonylvaline	158961-81-0
Tubulicid red	161445-62-1
SALES SPECIFICATION	
APPEARANCE	yellowish wax
ACID VALUE	3 max
IODINE VALUE	61 - 71
TRANSPORTATION	
PACKING	20kgs/can
HAZARD CLASS	
UN NO.	
OTHER INFORMATION	

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## LUMULSE™ PGO K Polyglycerol Ester

### Chemical Description:

LUMULSE PGO K is manufactured to meet the Kosher requirements designated by the Orthodox Union (OU).

### Chemical Name:

Triglycerol monooleate

### CAS Number:

68605-19-6

### Lambent Technologies

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LUMULSE is a trademark of Petroform Inc.

# Technical Data Sheet

## Product Description and Applications

LUMULSE PGO K is a polyglycerol ester prepared from glycerine and edible oils or fatty acids. It is an oil soluble emulsifier and multi-purpose additive for food products.

LUMULSE PGO K is derived from naturally renewable resources and may be used to replace ethylene oxide based surfactants.

Ice Cream - LUMULSE PGO K is an efficient, easy-to-handle liquid emulsifier. It provides controlled overrun, drier freezer texture and smoother frozen product for both commercial and counter freeze use. It works equally well for high or low butterfat ice creams and vegetable fat frozen products.

Bakery Specialities - LUMULSE PGO K enhances surface active properties of fats and oils in coatings, icing bases, fillings, mixes, flavor emulsions, baking pan release compounds and bakers' hydrate pastes.

Margarine and Shortenings - LUMULSE PGO K enables effective emulsification of liquid oils as well as harder fats. Liquid shortenings formulate readily with LUMULSE PGO K.

Miscellaneous - The bland flavor of LUMULSE PGO K makes it suitable for use in dietary and other edible fat emulsions, beverage bases and vitamin concentrates containing oil-soluble constituents.

LUMULSE PGO K conforms to 21 CFR 172.854

## Specifications

### Limits

Appearance at 25°C (77°F)	Clear liquid
Acid Value, mg KOH/gram	6 max.
Saponification Value, mg KOH/gram	125-150

## Typical Properties

Color, Gardner	7
Odor	Bland
Taste	Bland
Iodine Value, cg Iodine/gram	100
HLB	7
Specific Gravity at 25°C (77°F)	0.97
Density, lbs./gallon	8.1

LUMULSE PGO disperses in water and is soluble in vegetable oil, mineral oils and isopropyl alcohol.

## Storage and Handling

Standard sample size is 8 oz.  
55 gal. non-refundable drum, 440 lbs. (200 kg) net  
5 gal. pail, 44 lbs. (20 kg) net

## Packaging

LUMULSE PGO K should be stored in closed, factory sealed containers at temperatures below 90°F (32°C). Product should be used within one year of date of delivery.

Please refer to the Material Safety Data Sheet (MSDS) for this product for instructions on safe and proper handling and disposal.

NON WARRANTY: The data and statements contained herein are based on our research and/or the research of others, and are believed to be accurate. No guarantee of their accuracy is made however, and unless expressly stated in a written contract, the product(s) discussed herein are sold without conditions or warranties, expressed or implied. Purchasers are advised to make their own tests to determine the suitability of this product for their particular purposes. Nothing contained herein shall be construed as a recommendation to use or as a license to operate under or to infringe on any existing patent.